510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax Number of Applicant

Spine View, Inc.
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Fremont, CA 94538
Phone: (510) 623-1931
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B. Contact Person

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Director Quality and Regulatory
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mmuthini@spineview.com

C. Date Prepared

March 5, 2012

D. Device Name

Trade Name:	enSpire™ Discectomy System
Common Name:	Arthroscope & Accessory
Classification Name:	Arthroscope & Accessories (21 CFR §888.1100, Product Code HRX)

E. Predicate Devices

The modified enSpire™ Discectomy System is substantially equivalent to the Spine View enSpire™ Discectomy System cleared under K110992 on October 21, 2011.

F. Device Description

The modified enSpire™ Discectomy System is a single-use discectomy device that is designed to cut and grind intervertebral disc material. An auger mechanism retrieves the excised debris and ejects it into a collection chamber.

The modified enSpire™ Discectomy System is supplied as a sterile, single patient use, disposable device.

G. Intended Use

The modified enSpire™ Discectomy System is intended for use in cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.

H. Technological Comparison

The modified enSpire™ Discectomy System has similar features compared to the predicate devices in the table below.

Manufacturer	Spine View, Inc.	Spine View, Inc.
Device Name	enSpire™ Discectomy System	Modified enSpire™ Discectomy System
510(k) Number	K110992	TBD
Indications for Use	The enSpire™ Discectomy System is intended for use in cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.	Same
Product Code	HRX Arthroscope, 21CFR888.1100, Class II, (Debrider)	Same
Principal Operator	Physician	Same
Use Location	Operating Room or Medical Suite	Same
Operating Principal	Percutaneous, endoscopic or open surgical Discectomy system with standard surgical accessories	Same
Functions of Included Devices	Dilatation Access Excision Aspiration	Same
Mechanics of Action	Activating the device causes the cutting mechanism to expand and rotate and auger to rotate to cut and grind the disc material, which is then aspirated down the working shaft of the device and collected in the collection chamber	Activating the device causes the auger to rotate against the entrapped tissue and fixed cutting mechanism to cut and grind the disc material, which is then aspirated down the working shaft of the device and collected in the collection chamber
Target Anatomy	Cervical, Thoracic and Lumbar spinal segments	Same
Design Features	Auger housed in a tube with expandable rotating cutting assembly (spiral wire or curette style cutter) on the distal end. Driven by a battery-powered motor that is housed in a plastic handle at the proximal end of the	Auger housed in a tube with a non-expandable Serrated Cutting Window at the distal end. Driven by a battery-powered motor that is housed in a plastic handle at the proximal end of the device.

Manufacturer	Spine View, Inc.	Spine View, Inc.
Device Name	enSpire™ Discectomy System	Modified enSpire™ Discectomy System
510(k) Number	K110992	TBD
	device. Cut debris can pass up the tube and into the collection chamber located at the end of the auger. It is inserted into the surgical site either directly, via an introducer cannula or Arthroscope. The device contains a straight, curved or articulating working shaft. Expandable spiral wire and a curette style cutter Sweep Diameter (Expanded): 0.280 – 0.390"	Cut debris can pass up the tube and into the collection chamber located at the end of the auger. It is inserted into the surgical site either directly, via an introducer cannula or Arthroscope. The device contains a straight or articulating working shaft. Non-Expandable Serrated Cutting Windows SV3309: 0.075" x 0.240" x 2 windows SV1107: 0.055" x 0.170" x 2 windows
Tip Materials	PEEK, Aramid Fiber, Polyimide, Stainless Steel, and Tungsten	Stainless Steel
Sterile Packaging	The enSpire™ Discectomy System is placed into a thermo formed tray with a thermoformed insert lid, and sealed with a Tyvek tray lid. The sealed tray is then placed in a labeled chip board shelf carton.	Same
Sterilization Method	Gamma	Same
Biocompatible for Intended Use	Yes	Yes
Single use	Yes	Yes
Configuration	Straight, Curved, Articulating	Straight or Articulating
Handle Design	Hand-held rotary device, in-line or pistol-grip handle	Same
Profile	0.046-0.165" OD working shaft with tip 0.280-0.400" OD deployed, 0.058-0.220" OD unexpanded	0.058-0.110" OD shaft diameter at tip
Working Length	2 -22" working length	2 -9" working length
Energy Type	Mechanical	Same
Power	Battery, 9V or 18V	Same
Meets Applicable IEC60601-1 testing	Yes	Yes
User visualization/guidance	Direct visualization, fluoroscopic imaging or other imaging modalities.	Same

The technological characteristics and principals of operation of the modified enSpire™ Discectomy System are substantially equivalent to the named predicate device.

I. Summary of Non-Clinical Data

The modified enSpire™ Discectomy System performance characteristics were evaluated in the following in-vitro bench studies:

- Cannula Compatibility
- Enable Switch Durability
- Deployment & Retraction
- Working Shaft Length
- Device Durability
- Travel Limiter Attachment
- Travel Limiter
- Tensile Strength
- Articulation Function
- Articulation Angle
- Visualization
- Peak Temperature during Operation
- Tissue Volume/Material Removal
- No Breach of Annulus or Endplates
- Electromagnetic Compatibility and Electrical Safety
- Packaging Testing
- Shipping Testing
- Sterility Testing
- Shelf Life Testing
- Biocompatibility:
  - Cytotoxicity
  - Sensitization
  - Irritation
  - Systemic Toxicity

Results of the pre-clinical testing demonstrate that the materials chosen, the manufacturing process, and design of the modified enSpire™ Discectomy System meet the established specifications necessary for consistent performance during its intended use. In addition, the testing demonstrates the modified enSpire™ Discectomy System is substantially equivalent to the named predicate.

J. Summary of Data

The modified enSpire™ Discectomy System has been carefully compared to a legally marketed device with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to validate the performance of the device and ensure the modified enSpire™ Discectomy System performs as intended and meets the design specifications. The non-clinical performance testing and comparison to the predicate device demonstrate that the modified enSpire™ Discectomy System is substantially equivalent to the predicate device and does not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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JUN 2 6 2012

Re: K120680
Trade/Device Name: enSpire™ Discectomy System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope & Accessory
Regulatory Class: Class II
Product Code: HRX
Dated: June 15, 2012
Received: June 18, 2012

Dear Ms. DeGregorio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

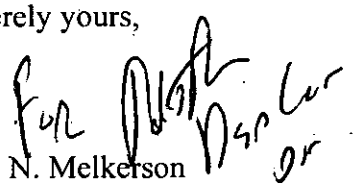
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K K120680

Device Name: enSpire™ Discectomy System

Indications for Use:

The enSpire™ Discectomy System is intended for use in cutting, grinding and aspirating intervertebral disc material during discectomy procedures in the cervical, thoracic and lumbar spine.

Prescription Use ___X___ **OR** **Over-The-Counter Use**_____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120680